05 1517

No. 05-

Supreme Court, U.S.
FILED
MAY 26 2006
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FREDRIC A. STERN,

Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and LASZLO Z. BITO,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

DONALD W. NILES
NILES LAW OFFICE, P.A.
1920 Summit Avenue
St. Paul, Minnesota 55402
(651) 699-5650

Counsel for Petitioner

201160

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

1. Whether joint inventorship under 35 U.S.C. § 116 requires physical presence or participation of each inventor in the last of a series of experiments reflected in only one of several claim limitations in order to be a co-inventor?

2. Whether a peer-reviewed scientific journal article, portions of which are copied verbatim into the body of the patent and reflect conception of multiple elements of one or more claims of the patent, may be corroborating evidence of the co-inventorship of the lead author of the article?

3. Whether a claim of omitted co-inventorship under 35 U.S.C. § 256 may be summarily dismissed as a matter of law without analysis of the non-moving party's claimed contributions to the patent or whether those claimed contributions are found within the language of the claims of the patent?

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

TABLE OF CONTENTS ii

TABLE OF CITED AUTHORITIES iv

OPINIONS BELOW 1

STATEMENT OF JURISDICTION 1

STATUTORY PROVISIONS INVOLVED 1

STATEMENT OF THE CASE 3

REASONS FOR GRANTING THE PETITION ... 4

A. JOINT INVENTORSHIP UNDER 35 U.S.C. § 116 IS AN IMPORTANT ISSUE OF NATIONAL IMPORTANCE THAT DOES NOT HINGE ON PHYSICAL PRESENCE OR PARTICIPATION IN THE LAST OF A SERIES OF EXPERIMENTS REFLECTED IN ONLY ONE OF FOUR CLAIM LIMITATIONS 4

B. LEAD AUTHORSHIP OF A PEER-REVIEWED SCIENTIFIC JOURNAL ARTICLE, PORTIONS OF WHICH ARE COPIED VERBATIM INTO THE BODY OF THE '353 PATENT AND REFLECT CONCEPTION OF ELEMENTS OF THE CLAIMS, MAY BE CORROBORATING EVIDENCE OF CO-INVENTORSHIP 8

Contents

Page

C. A CLAIM OF OMITTED CO-INVENTORSHIP UNDER 35 U.S.C. § 256 MAY NOT BE SUMMARILY DISMISSED WITHOUT ANALYSIS OF THE NON-MOVING PARTY'S CLAIMED CONTRIBUTIONS TO THE CONCEPTION OR WHETHER THE NON-MOVING PARTY'S CLAIMED CONTRIBUTIONS ARE FOUND WITHIN THE LANGUAGE OF THE CLAIMS OF THE PATENT 10

CONCLUSION 14

TABLE OF CITED AUTHORITIES

Page

CASES

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242, 106 S.Ct. 2505 (1986) 12, 14

Burroughs Wellcome Co. v. Barr Labs, Inc.,
40 F.3d 1223 (Fed. Cir. 1994) 6, 7

Eli Lilly & Co. v. Aradigm Corp.,
376 F.3d 1352 (Fed. Cir. 2004) 6

Ethicon, Inc. v. United States Surgical Corp.,
135 F.3d 1456 (Fed. Cir. 1998) 6, 7, 10, 11, 13

Fina Oil & Chemical Co. v. Ewen,
123 F.3d 1466 (Fed Cir. 1997) 7

In Re Katz,
687 F.2d. 450 (C.C.P.A. 1982) 8, 9, 10

Price v. Symsek,
988 F.2d 1187 (Fed. Cir. 1993) 11

Trovan, Ltd. v. Sokymat SA,
299 F.3d 1292 (Fed. Cir. 2002) 7

Cited Authorities

Page

University of Colorado Foundation, Inc. v. American Cyanamid Co., 342 F.3d 1298 (Fed. Cir. 2003) 10

University of Colorado Foundation, Inc. v. American Cyanamid Co., 105 F.Supp.2d. 1164 (D. Colo. 2000) 10

STATUTES

35 U.S.C. § 116 ..... i, 1, 4, 6, 14

35 U.S.C. § 256 ..... i, 2, 3, 10

Petitioner Fredric A. Stern petitions this Court for writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The Federal Circuit's opinion (Pet. App. 1a) is reported at 434 F.3d 1375. The District Court's opinion and order (Pet. App. 6a) is unreported. The order of the Federal Circuit denying the petition for rehearing and for rehearing en banc (Pet. App. 25a) is unreported.

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Federal Circuit from which petitioner seeks review was issued on January 17, 2006. The jurisdiction of this Court is pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The patent inventorship statute, 35 U.S.C. § 116, provides:

> Sec. 116. Inventors
>
> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

If a joint inventor refuses to join in an application for patent or cannot be found or reached after diligent effort, the application may be made by the other inventor on behalf of himself and the omitted inventor. The Director, on proof of the pertinent facts and after such notice to the omitted inventor as he prescribes, may grant a patent to the inventor making the application, subject to the same rights which the omitted inventor would have had if he had been joined. The omitted inventor may subsequently join in the application.

Whenever through error a person is named in an application for patent as the inventor, or through error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

The correction of patent inventorship statute, 35 U.S.C. § 256, provides:

Sec. 256. Correction of named inventor

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issued a certificate correcting such error.

> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

STATEMENT OF THE CASE

After learning his award-winning laboratory work and published peer-reviewed paper were copied verbatim within and used by Appellees to obtain United States Patent No. 4,599,353, "Use of eicosanoids and their derivatives for treatment of ocular hypertension and glaucoma" ("'353 Patent"), Dr. Fredric A. Stern brought this action seeking correction of inventorship pursuant to 35 U.S.C. § 256. Dr. Stern seeks co-inventorship of the '353 Patent and asserts state law claims of fraud, unjust enrichment and breach of fiduciary duty. (A29, A35-A39).[1] The '353 Patent covers a Pfizer drug called Xalatan®, its genesis in NIH-sponsored research and now the most frequently prescribed glaucoma treatment in the world.

Stern filed his Complaint on November 14, 2001 (A13), and discovery proceeded. On December 27, 2002, Appellees-Defendants served a motion for summary judgment, which was fully submitted on January 21, 2003 to the district court, Honorable Richard Conway Casey, Southern District of New York. (A16). The district court took no oral argument, and

---

1. Citations in the form of A29 and the like refer to the appendix on appeal before the Federal Circuit.

the matter was decided on the briefs by an Opinion and Order dated February 17, 2005. (Pet. App. 6a). The Federal Circuit issued a published precedential opinion on January 17, 2006 affirming the district court. (Pet. App. 1a).

REASONS FOR GRANTING THE PETITION

A. Joint Inventorship under 35 U.S.C. § 116 Is an Important Issue of National Importance that Does Not Hinge on Physical Presence or Participation in the Last of a Series of Experiments Reflected in Only One of Four Claim Limitations.

The correct application of the law of inventorship, 35 U.S.C. § 116, is an important question of national importance. Inventorship is fundamental to the patent law, both as to correct issuance of patents and in subsequent validity challenges to issued patents frequently asserted in litigation. The Federal Circuit erroneously adopted the Appellees' argument that each inventor must collaborate in the final experiment in a series of experiments reflecting conception in order to be a co-inventor.

Independent Claim 1 of the '353 Patent provides:

> A method for treating hypertension of or glaucoma in a primate subject's eye comprising periodically contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any substantial initial increase in said pressure and to maintain reduced intraocular pressure.

(A27).

Both sides' experts agreed there are essentially four elements to Claim 1 of the '353 Patent (A278-A280), as follows:

A method for treating hypertension or glaucoma in a primate subject's eye comprising:

1. periodically contacting the surface of the eye with an amount of an eicosanoid or eicosanoid derivative;
2. effective to reduce intraocular pressure in the eye;
3. without any substantial initial increase in said pressure; and
4. to maintain reduced intraocular pressure.

(*See also* A27).

Stern's experimental discovery was first reported by Stern as the sole author in two written research papers (A828; A845), and then later published in a peer-reviewed scientific journal. STERN & BITO, "*A Comparison of the Hypotensive and Other Ocular Effects of Prostaglandins E_2 and $F_{2\alpha}$ on Cat and Rhesus Monkey Eyes*," *Investigative Ophthalmology & Visual Science* pp. 588-98 (submitted May 18, 1981; published May 1982) (A762-A773) (hereafter "STERN & BITO ARTICLE"). Stern ought be added as a co-inventor of the '353 Patent because Elements 2 and 3 were discovered and established by Stern's experiments on Rhesus monkeys and cats, experiments embodied and referred to as "Experiment 2" in the '353 Patent.

Appellees argued, and the Federal Circuit agreed, that an experiment commenced by Appellee Bito in June 1981 ("Experiment 3"), which confirmed for Appellee Bito that Stern's results could be repeated over a period of 21 days was necessary for "complete" conception. *See* Opinion (Pet. App. 2a) ("After Stern's departure from Columbia, Bito conceived the '353 patent while studying the effects of repeated prostaglandin application on the IOP in rhesus monkeys."), (Pet. App. 4a-5a) (citing *Burroughs*).

Supreme Court review is necessary to correct the Federal Circuit's plainly erroneous construction and application of the controlling statute, 35 U.S.C. § 116. The Federal Circuit's decision was in plain contravention of the express language of 35 U.S.C. § 116 and related case law:

> (a) "Inventors may apply for a patent jointly even though (1) *they did not physically work together or at the same time*, (2) *each did not make the same type or amount of contribution*, or (3) each did not make a contribution to the subject matter of every claim of the patent."

35 U.S.C. § 116 (emphasis added).

> (b) "[T]he law of inventorship *does not hinge co-inventor status on whether a person contributed to the conception of all the limitations in any one claim of the patent*. Rather, the law requires only that a co-inventor make a contribution to the conception of the subject matter of a claim."

Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1361-62 (Fed. Cir. 2004) (citing 35 U.S.C. § 116 and *Ethicon*, 135 F.3d at 1461-63) (emphasis added).

(c) "*One need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship.*"

Fina, 123 F.3d at 1473 (emphasis added); *see Ethicon*, 135 F.3d at 1461-63.

(d) It is reversible error to focus on a single claim limitation and ignore other claim limitations in determining a claim of joint inventorship.

Trovan, Ltd. v. Sokymat SA, 299 F.3d 1292, 1306 (Fed. Cir. 2002).

(e) The doctrine of simultaneous conception and reduction to practice:

"cannot be used . . . to show that because the first person did not conceive or reduce to practice the entire claimed invention, he or she did not contribute to the ultimate conception."

Fina, 123 F.3d at 1474.

Assuming *arguendo* that element 4, "to maintain reduced intraocular pressure" or absence of tachyphylaxis, was a necessary showing for co-inventorship, the record in this case nevertheless reveals issues of fact on that issue: (1) the record reflects Stern and Bito had discussions planning Experiment 3 (A1341); (2) Bito immediately started Experiment 3 following Stern's experiment (A108; A1129; A1239 (ln. 14-15)); and (3) Experiment 3 simply repeated Stern's experiment for 20 days using the same doses of PGs Stern discovered to be effective without an initial spike in IOP (*see* Appellant's Brief at 13-14, 49) — Stern's discovery in Experiment 2 was "*sufficient to practice* the invention," *Burroughs*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (emphasis added).

Moreover, the Federal Circuit ignored that Appellee Columbia expressly represented to the Patent Office that the Stern & Bito Article "shows the effect in a primate eye of periodic, topical application of prostaglandins in reducing intraocular pressure *and in maintaining reduced intraocular pressure*." (A551) (emphasis added); *see also* (A1014) (Bito statement to NIH).

B. Lead Authorship of a Peer-Reviewed Scientific Journal Article, Portions of which Are Copied Verbatim into the Body of the '353 Patent and Reflect Conception of Elements of the Claims, May Be Corroborating Evidence of Co-Inventorship.

Stern was one of only two authors, and the lead author, of the STERN & BITO ARTICLE. Case law indicates co-authorship itself does not raise a "presumption" of inventorship, but likewise makes clear that authorship can be used as evidence of co-inventorship and cannot be ignored as the Federal Circuit did here.

> *[T]he article may or may not raise a substantial question* whether the applicant is the inventor. * * * *The content and nature of the printed publication, as well as the circumstances surrounding its publication, not merely its authorship must be considered.*

In re Katz, 687 F.2d 450, 455 (C.C.P.A. 1982) (emphasis added). Moreover, there is not even an inventor's affidavit (*Katz* affidavit) in the file history of the '353 Patent specifically disclaiming Dr. Stern's contribution to the '353 Patent. Further, Stern was not only lead author but the undisputed first person to describe these experiments in his sole author papers for which he received an award from Columbia University for his research work. (A828-A844; A845-A861).

Here Stern presented the following additional facts, which like the fact portions of the STERN & BITO ARTICLE copied verbatim into the '353 Patent, were ignored in the Federal Circuit's opinion:

1. In the Ophthalmology field specifically, first author status is significant because the prestigious ophthalmology scientific research organization, ARVO, allows only first author presentation of collaborative research at ARVO's annual convention. (A1186);

2. The guidelines for authorship of the International Committee of Medical Journal Editors indicate first author status is for the primary contributor to the reported work. (A1184; *see* A1124);

3. Appellee Bito's May 1981 student evaluation of Dr. Stern acknowledged Stern "wrote the entire first draft of the manuscript." (A338; A41);

4. The STERN & BITO ARTICLE *followed* two student research papers, *written by Stern alone*, in which Stern reported his discovery and, specifically, that:

> These observations clearly suggest the[sic] that the PGs and/or their more stable analogues may prove to be useful therapeutic agents for the treatment of glaucoma.

(A830).

Even in the procedural posture of a patent application appeal in *Katz*, it was recognized that the content and nature of the publication as well as the circumstances surrounding

its publication "*must be considered.*" 687 F.2d at 455 (emphasis added). Additionally, the Federal Circuit has agreed with a district court's conclusion that the "wholesale copying" of a manuscript into a patent can be "compelling corroborative evidence" of inventorship. *University of Colorado*, 342 F.3d at 1304 & 1309; *see University of Colorado Foundation, Inc. v. American Cyanamid Co.*, 105 F.Supp.2d. 1164, 1182 (D. Colo. 2000).

C. A Claim of Omitted Co-inventorship under 35 U.S.C. § 256 May Not Be Summarily Dismissed Without Analysis of the Non-moving Party's Claimed Contributions to the Conception or Whether the Non-moving Party's Claimed Contributions Are Found Within the Language of the Claims of the Patent.

In *Ethicon*, the Federal Circuit described the required analysis for a claim of joint inventorship:

> To determine whether [the putative inventor] made a contribution to the conception of the subject matter of [the claim], this court must determine what [the putative inventor's] contribution was and then whether that contribution's role appears in the claimed invention. If [the putative inventor] in fact contributed to the invention defined by [the claim], he is a joint inventor of that claim.

135 F.3d at 1461. Despite *Ethicon*, the Federal Circuit here simply issued findings of fact commenting on only one lesser piece of offered evidence, Dr. Bito's authorizing the destruction of the lab notebooks containing the experiments that are the basis of this patent. *See* Opinion (Pet. App. 5a).

This was error under *Ethicon* and *Price v. Symsek*, 988 F.2d 1187, 1196 (Fed. Cir. 1993). "'*[A]ll of the evidence put forth' should have been considered and acknowledged. . . .*" *Ethicon*, 135 F.3d at 1461 (quoting *Price*, 988 F.2d at 1196) (emphasis added).

The following evidence was not discussed or analyzed by the Federal Circuit: (1) Evidence that Bito had abandoned research on PGs as a treatment for glaucoma prior to Stern's experimental discovery (Appellant's Fed. Cir. Appeal Brief at 5-8, 37-40); (2) that Stern's experimental discovery showed patentable elements of the '353 Patent for the first time (*id.* at 9-12); (3) that Stern's discovery led Bito to make immediate major changes in allocation of personnel and resources (*id.* at 12-15); (4) that Appellees' patent application copied whole portions of the STERN & BITO ARTICLE, comprising five full pages of the original '353 Patent application (*id.* at 15-16); (5) that the Patent Office file history shows the "absence of initial spike in IOP" claim limitation discovered by Stern was necessary to obtain the patent (*id.* at 9-12); (6) that while claiming just the opposite in this case, to obtain the '353 Patent Appellees expressly stated to the Patent Office that Bito's work preceding Stern's experiment "teaches away from the claimed invention for several reasons" (A533) and that Stern's experiment was an "unexpected" discovery (A534); (7) that Columbia University awarded Stern its highest student award for outstanding ophthalmology research, even though Stern was not a member of that department and this was his only work in the area (Appellant's Brief at 10, 44-45); and (8) that Bito wrote to the University of Washington stating, "[Stern's] project [was] *an integral part of our studies on the development and use of eicosanoids for the treatment of glaucoma. . . .*" (A988) (emphasis added);

The fact-finding of the Federal Circuit violates the standards for summary judgment set forth by this Court:

> It by no means authorizes trial on affidavits. Credibility determinations, the weighing of evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge. . . . *The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.*

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 2513 (1986) (emphasis added).

The inferential fact-finding engaged in by the Federal Circuit not only violated the standards for summary judgment, but is actually contradicted by the positive evidence of record in this case as the following examples demonstrate:

(1) *Compare* the Federal Circuit's finding that "Stern did not have an understanding of the claimed invention" (Pet. App. 5a) *with* Stern's contemporaneous writings:

> "These observations clearly suggest the[sic] that the PGs and/or their more stable analogues may prove to be useful therapeutic agents for the treatment of glaucoma." (A830 (one of Stern's sole author research papers)); and
>
> "Thus PGs or their analogues may provide a new approach to the clinical control of IOP and the treatment of glaucoma." (A339 (STERN & BITO ARTICLE); *also id.* at A348).

(2) The Federal Circuit's finding Stern "did not discover that prostaglandins have an effect on IOP" (Pet. App. 5a) is not part of the claim and is not something Bito discovered either, being reflected in published prior art (A348 n.1-4) going back many years preceding Stern's experimental discovery.

(3) *Compare* the Federal Circuit's finding that Stern "did not discover that repetitive application of prostaglandins to the eyes of primates can maintain reduced IOP" (Pet. App. 5a) *with* Appellee's successful file history argument to obtain the '353 Patent that the STERN & BITO ARTICLE:

> "shows the effect in a primate eye of periodic, topical application of prostaglandins in reducing intraocular pressure *and in maintaining reduced intraocular pressure*." (A551) (emphasis added); *see also* (A1014) (Bito statement to NIH).

In *Ethicon*, the Federal Circuit *affirmed a judgment of co-inventorship based on far less corroborating evidence than Dr. Stern presented* in response to Appellees' summary judgment motion. In *Ethicon*, a judgment finding omitted co-inventorship was affirmed based only on the testimony of the named inventor, the omitted co-inventor, and hand-written sketches. *Ethicon*, 135 F.3d at 1464.

Like *Ethicon*, here Stern's two sole-author research papers written to apply for Columbia's McKane Award show Stern's contributions textually and graphically. (A828-A844; A845-A861). In its totality, Stern submitted a body of evidence, including his own testimony, that was far more substantial than

the Federal Circuit found sufficient to affirm a judgment of co-inventorship in *Ethicon*. In the posture of a summary judgment motion, therefore, Stern should not have been deprived of his day in court. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 2513 (1986).

CONCLUSION

Dr. Stern designed, implemented, analyzed and first reported Experiment 2 as it is identified in the '353 Patent. According to the file history of the '353 Patent, Dr. Stern's 1981 research resulted in an "unexpected" discovery demonstrating 3 of the 4 elements of Claim 1. Experiment 2 is undisputedly the first experiment ever to show a reduction in IOP in primates without an initial spike. Despite this experiment being directly copied into and referenced in the '353 Patent and the first experiment to ever show elements 2 and 3 of claim 1, the Federal Circuit held it to be of no-inventive significance. This is a clear error under 35 U.S.C. § 116, let alone in the posture of a summary judgment where all facts and reasonable inferences were to be construed in favor of Dr. Stern. Correct construction of the controlling patent inventorship statute, the evidence relevant to that determination, and correct application of this Court's summary judgment standard warrant Supreme Court review.

Respectfully submitted,

DONALD W. NILES
NILES LAW OFFICE, P.A.
1920 Summit Avenue
St. Paul, Minnesota 55402
(651) 699-5650

Counsel for Petitioner

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED JANUARY 17, 2006

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1291

FREDRIC A. STERN,

Plaintiff-Appellant,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and LASZLO Z. BITO,

Defendants-Appellees.

DECIDED: January 17, 2006

Before MAYER, RADER, and LINN, Circuit Judges.

MAYER, Circuit Judge.

Frederic A. Stern appeals the judgment of the United States District Court for the Southern District of New York granting the Trustees of Columbia University in the City of New York's and Laszlo Z. Bito's (collectively "Columbia's") motion for summary judgment that Stern failed to present sufficient evidence to be added as co-inventor of United States Patent No. 4,599,353 ("the '353 patent"). *Stern v. Trs.*

Appendix A

of Columbia Univ., No. 01-CV-10086 (S.D.N.Y. Feb 17, 2005). We affirm.

Background

Columbia University is the owner of the '353 patent, which is directed towards the use of prostaglandins in treating glaucoma. Lazlo Z. Bito is the named inventor of the '353 Patent, and was a long-time faculty member at Columbia University. In 1980, while Stern was a medical student at Columbia University, he approached Bito about doing a one semester ophthalmology research elective in his laboratory. Bito agreed and directed Stern to begin his project by reviewing Bito's papers on prostaglandins and intraocular pressure ("IOP"). At that point, Bito had published numerous papers on the effects of prostaglandins on the IOP in various animals, notably rabbits and owl monkeys, and had concluded that rhesus monkeys would be good subjects for further studies on the effects of prostaglandins on IOP. Experiments Stern conducted while working in Bito's laboratory showed that topical application of a single dose of prostaglandin reduced IOP in rhesus monkeys and cats. Stern's experiments did not prove whether tachyphylaxis would develop in primates, the absence of which is required for successful glaucoma treatment. After Stern's departure from Columbia, Bito conceived the '353 patent while studying the effects of repeated prostaglandin application on the IOP in rhesus monkeys. Bito applied for the patent in 1982 and, in 1986, it was issued. Claim 1 states:

> [a] method for treating hypertension or glaucoma in a primate subject's eye comprising periodically contacting the surface of the eye with an amount

> of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any substantial initial increase in said pressure and to maintain reduced intraocular pressure.

'353 col. 16, II.5-11.

When Stern found out about the '353 patent, he brought suit seeking to be added to the patent as a co-inventor of the patent's independent claim one and dependent claims 3, 5, and 9 through 12. Stern also asserted state law claims for fraudulent concealment, breach of fiduciary duty, and unjust enrichment.

In determining inventorship, the trial court first construed the claims of the '353 patent. The only disputed phrase was the meaning of "to maintain reduced intraocular pressure" in claim 1. The trial court found that Columbia's proposed construction of the phrase to mean "maintenance of reduced intraocular pressure throughout the course of treatment without development of tachyphylaxis, i.e., throughout the period of time that the claimed method is being used to treat glaucoma" was correct. Using that construction, the trial court determined that Stern failed to present clear and convincing evidence of inventorship, as required to be added as a co-inventor to a published patent. *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004). Accordingly, the trial court granted Columbia's motion for summary judgment. Because the state law claims for fraudulent concealment, breach of fiduciary duty, and unjust enrichment depended on the addition of Stern as a co-inventor of the

'353 patent, the trial court also granted summary judgment to Columbia on those claims. We have jurisdiction pursuant to 28 U.S.C. § 1295(a).

Discussion

We review the district court's grant of summary judgment de novo. *See Caterpillar Inc. v. Sturman Indus.*, 387 F.3d 1358, 1373 (Fed. Cir. 2004). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Because a patent carries a statutory presumption of validity, 35 U.S.C. § 282, Stern had the burden of showing by clear and convincing evidence, after all reasonably inferences were drawn in his favor, that he was an inventor of the '353 patent.

Because "[c]onception is the touchstone of inventorship," each joint inventor must generally contribute to the conception of the invention. *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). Additionally, courts require corroborating evidence of conception. *Id.* at 1228. However, contribution to one claim is sufficient to be a co-inventor. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). Conception is defined as "the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (citation omitted). Conception

is complete when "the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome*, 40 F.3d at 1228.

Here, Stern did not have an understanding of the claimed invention, did not discover that prostaglandins have an effect on IOP, did not discovery that repetitive application of prostaglandins to the eyes of primates can maintain reduced IOP, and did not conceive of the idea of the use of prostaglandins to reduce IOP in primates. Furthermore, there was no collaboration between Stern and Bito in developing a glaucoma treatment. Stern simply carried out an experiment previously done by Bito on different animals—animals that Bito had already determined would be good models for prostaglandins research. Stern's contribution is insufficient to support a claim of co-inventorship.

Stern also argues that material in his laboratory notebooks would have provided his claim of co-inventorship, but that they were destroyed by Bito. However, regardless of the contents of the notebooks, unwitnessed laboratory notebooks on their own are insufficient to support his claim of co-inventorship. *See Hybritech*, 802 F.3d at 1378. Thus, the evidence Stern presented was insufficient to corroborate his claim of co-inventorship.

Conclusion

Accordingly, the judgment of the United States District Court for the Southern District of New York is affirmed.

AFFIRMED

APPENDIX B — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED FEBRUARY 17, 2005

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

01 Civ. 10086 (RCC)

FREDERIC A. STERN,

Plaintiff,

– against –

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and LASZLO Z. BITO,

Defendants.

OPINION AND ORDER

RICHARD CONWAY CASE, United States District Judge:

Plaintiff Dr. Frederic A. Stern ("Plaintiff" or "Stern") commenced this suit for correction of inventorship of United States Patent 4,599,353 ("the '353 Patent" or the "the Patent"), pursuant to 35 U.S.C. § 256, and fraud, unjust enrichment, and breach of fiduciary duty arising under New York common law. The '353 Patent protects the discovery that periodic applications of prostaglandins to the eyes of primates reduces intraocular pressure without causing a substantial initial increase in pressure or resistance to the treatment. The Patent has lead to the development of

prescription drug treatment of glaucoma in humans. Defendant Columbia University ("Columbia") is the owner of the '353 Patent and Defendant Dr. Laszlo Bito ("Bito") is listed as the Patent's sole inventor (collectively "Defendants"). Defendants move for summary judgment pursuant to Federal Rule of Civil Procedure 56. For the reasons explained, Defendants' motion is granted.

I. Background

Unless otherwise noted, the following facts are not in dispute. Glaucoma patents typically experience increased fluid pressure in their eyes, known as intraocular pressure, which damages the optic nerve and can eventually lead to blindness. Plaintiff's Rule 56.1 Statement (hereinafter "Pltf. 56.1)" ¶¶ 1-2. Dr. Bito, now a recognized expert in the field of glaucoma research, joined the Columbia faculty in the Department of Ophthalmology in 1966 and began researching the relationship between intraocular eye pressure and prostaglandins, which are a type of chemical compound known as eicosanoids. *Id.* ¶¶ 3, 6, 10. At the time there were scientific reports that prostaglandins produced an undesirable increase in intraocular pressure. *Id.* ¶ 4.

In 1977, Dr. Bito and others published the results of his experiments showing that a single low dose of a prostaglandin could reduce intraocular pressure in rabbit eyes without a substantial initial increase in pressure. *Id.* ¶¶ 13-14. Dr. Bito directed a subsequent study on rabbits, however, that demonstrated periodic topical applications resulted in tachyphylaxis or drug tolerance. *Id.* ¶ 15. In 1978, Dr. Bito, along with medical student Carl Camras, topically administered

prostaglandins to the eyes of owl monkeys with glaucoma and found a single dose resulted in the reduction of intraocular pressure. *Id.* ¶ 16. Stern argues that the owl monkey studies also demonstrated an initial spike in intraocular pressure and that, as a result, Dr. Bito decided to "chuck" the data. *Id.* ¶¶ 16, 13. Defendants submit that owl monkeys were simply not the appropriate model to study the human eye's reaction to prostaglandins treatment. *Id.* ¶ 16. Based on experiments that he and others performed between 1977 and 1981, Dr. Bito believed that rhesus monkey and cats would be useful models to continue studying the effects of prostaglandins on intraocular pressure. *Id.* ¶ 17.

In the spring of 1981, while taking a research elective during his last year as a medical student at Columbia, Stern carried out experiments under Dr. Bito's supervision. *Id.* ¶ 19. Stern admits that prior to his work with Dr. Bito he had no previous experience in ophthalmology or glaucoma research, had never done any research with prostaglandins, and had never performed experiments using cats or rhesus monkeys. *Id.* ¶¶ 36-38. In Dr. Bito's lab, Stern topically applied a single dose of prostaglandin to the eyes of rhesus monkeys and cats, which was found to reduce intraocular pressure. *Id.* ¶ 18. Stern used animals already trained for lab use and applied prostaglandins that were already available in Dr. Bito's lab, in the amounts, and in the same manner, as had been used in earlier rabbit and owl monkey experiments. *Id.* ¶¶ 42, 43. Stern did no further work with prostaglandins after he left Dr. Bito's lab and graduated. *Id.* ¶¶ 46, 47, 49. Specifically, he did not do any work regarding the periodic application of prostaglandins. *Id.* ¶ 46.

Appendix B

In connection with his work in Dr. Bito's lab, Stern wrote a paper reporting the results of his experiments in which he is listed as the author and Dr. Bito is listed as the sponsor of the research. *Id.* ¶ 44. Dr. Bito suggested that Stern submit this paper to Columbia's Department of Ophthalmology and, as a result, Stern received the Edith and Denton McKane Memorial Award when he graduated. *Id.* Dr. Bito and Stern also worked together to modify the paper for publication in a peer-reviewed journal. *Id.*; *see also* F.A. Stern and L. Z. Bito, "Comparison of the Hypotensive And Other Ocular Effects of Prostaglandins E^2 and F^2cc On Cat and Rhesus Monkey Eyes," published in *Investigative Ophthalmology & Visual Science*, May 1982, at Niles Decl. Tab 6. The draft of the article Dr. Bito and Stern submitted to the journal is the same draft that Dr. Bito later submitted to the FDA in support of his notice of claimed investigational exemption for a new drug ("IND") in February 1982 Pltf. 56.1 ¶¶ 59, 60. In the IND, Dr. Bito explained that Stern was responsible for the day-to-day studies reflected in the paper. *Id.* ¶ 61. The published version of the article was also included in Columbia's application for the '353 Patent. *Id.* ¶ 45.

The parties agree that after Stern completed his experiments the question of tachyphylaxis remained. *Id.* ¶ 20. During the summer and fall of 1981, Dr. Bito and others conducted experiments demonstrating that the periodic application of prostaglandins did not cause tachyphylaxis in primates. *Id.* ¶ 22. Dr. Bito argues that he conceived the invention claimed in the '353 Patent during this course of experiments. Oct. 11, 2002 Bito Dep. at 17-18. Stern claims, however, that during his course of research he also

participated in the conception, design, and planning of these later experiments.

In May 1982, Dr. Bito applied for the '353 Patent. *Id.* ¶ 23. The '353 Patent contains the results of four experiments. *Id.* ¶ 26. Experiment 1 reports on the single dose studies on owl monkeys that Dr. Bito and others performed in the late 19702. *Id.* Experiment 2, in which Stern participated, reports on single dose studies performed in the spring of 1981 on rhesus monkeys and cats. *Id.* ¶ 27. Experiment 3 was conducted in the late summer of 1981, after Stern graduated, and consisted of repeated topical application of prostaglandins in the eyes of cats and rhesus monkeys. *Id.* As noted above, Stern contends that he participated in the planning and design of Experiment 3. *Id.* Experiment 4 concerns studies with prostaglandins and their derivatives. *Id.* ¶ 29.

After several rejections and amendments, the Patent and Trademark Office issued the '353 patent on July 8, 1986. Stern claims to be the co-inventor of claims one, three, five, and nine through twelve. The first claim explains that the Patent contains:

> [a] method for treating hypertension or glaucoma in a primate subject's eye comprising perio[illegible]lly contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any substantial initial increase in said pressure and to maintain reduced intraocular pressure.

'353 Patent, Claim 1. Claims three, five, nine, and ten are dependent on claim one and define the type of eicosanoid or derivative thereof to be used. Pltf. 56.1 ¶ 24. These substances were used in Dr. Bito's laboratory prior to Stern's work there. *Id.* Claims eleven and twelve are also dependent on claim one and recite the appropriate range of effective doses. *Id.* ¶ 25. Again, these doses were used in Dr. Bito's laboratory before Stern began his research there. *Id.* Stern claims, however, that he actually determined the effective dosages. *Id.*

Columbia granted an exclusive license under the '353 Patent to a predecessor of Pharmacia Corporation. In 1996, Pharmacia and its affiliates launched Xalatan, a prescription-only topical glaucoma treatment. Dr. Stern did not learn of the '353 Patent until the spring of 2001 when he was contacted by a party involved in an infringement suit based on the Patent. *Id.* ¶¶ 30-31.

II. Discussion

A. Summary Judgment Standard

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby*, 477 U.S. 242, 247 (1986); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1116 (Fed. Cir. 1985) (en banc). In the context of the pending motion, summary judgment is proper if the evidence, when viewed in the light most favorable to the non-moving party,

fails to establish the inventorship of an omitted inventor by clear and convincing evidence. *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1327 (Fed. Cir. 2004) (citing *Teleflex Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002)).

B. '353 Patent Claim Construction

The legal scope of a patent claim must be known before determining whether the correct inventors were named. *Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002); *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (holding claim construction is required only "when the meaning or scope of technical terms and words of art is unclear and in dispute"). The purpose of claim construction is to determine "the meaning and scope of the patent claims." *Markman v. Westview Instruments*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The court must give the disputed terms "their ordinary and accustomed meaning as understood by one of ordinary skill in the art." *Dow Chem. Co. v. Sumitomo Chem. Co. Ltd.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Optical Prods. Dev. Corp. v. Dimensional Media Assoc., Inc.*, 134 F. Supp. 2d 320, 326 (S.D.N.Y. 2001) (explaining "the hypothetical person of ordinary skill in the art is presumed, as a matter of law, to know of all prior art references in the same or analogous fields, regardless of his or her specific level of educational or vocational training") (citing *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991)).

The task of construction begins with an examination of the intrinsic sources. Intrinsic evidence includes the patent

itself, including the claims and specification, and the prosecution history. It is "the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). The words and phrases of the claims are to be given their ordinary and customary meaning. *Novo Nordisk A/S v. Becton Dickinson & Co.*, No. 96 Civ. 9506 (BSJ), 2000 WL 294852, at *1 (S.D.N.Y. Mar. 21, 2000). Any special definition must be clearly stated in the specification or history. *Vitronics Corp.*, 90 F.3d at 1582; *see also Intellectual Prop. Dev. v. UA Columbia Cablevision of Westchester, Inc.*, No. 94 Civ. 6296 (SS), 1998 WL 142346, at *21 (S.D.N.Y. Mar. 26, 1998) ("[T]he subjective intent of the inventor when using a particular term is of no probative weight in defining the scope of the claim . . . except as documented in the specification.").

The claims "must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979. The specification if defined by statute as the portion of the patent that includes the description of the invention. It "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112, ¶ 1. The claims define the limits of the invention. They must "particularly point out and distinctly claim" what the applicant regards as the invention. 35 U.S.C. § 112, ¶ 2; *Johnson Elec. N. Am. Inc. v. Mabuchi Motor Am. Corp.*, 77 F.Supp.2d 446, 450 n.2 (S.D.N.Y. 1999) (explaining the claims are also technically part of the specification, but

"general usage distinguishes between the specification and the claims as separate parts of the patent"). The prosecution history, which may include the record of proceedings before the PTO, the patentee's representations regarding the scope of the patent, and a review of the prior art, should also be considered. *Vitronics Corp.*, 90 F.3d at 1582 (finding prosecution history to be "of critical significance in determining the meaning of the claims").

Stern claims to be a co-inventor of the Patent's independent claim one and dependent claims three, five and nine through twelve. The parties' only dispute is the meaning of the phrase "to maintain reduced intraocular pressure" in claim 1. Stern contends the phrase should be read to mean reduction of intraocular pressure between periodic applications. Pltf. Claim Construction Brief at 6. Defendants assert the phrase should be interpreted as "maintenance of reduced intraocular pressure throughout the course of treatment without development of tachyphylaxis, i.e., throughout the period of time that the claimed method is being used to treat glaucoma." Def. Reply Claim Construction Brief at 3.

Stern contends defendants' definition requires the insertion of two distinct phrases – "through the course of treatment" and "without the development of tachyphylaxis" – without support of the specification. Stern also argues that Defendants' construction of the phrase is unduly limiting because "any drug otherwise falling under the '353 Patent which demonstrated any tolerance over time would fall outside the scope of the patent." Pltf. Claim Construction Brief at 6. The phase was added by an amendment purportedly

in effort to distinguish the claimed invention from the 1977 rabbit experiments that showed prostaglandins could reduce intraocular pressure. Plaintiff submits that Defendants tried to distinguish the patented invention from the rabbit experiments by arguing the earlier experiments produced an initial increase, followed by a decrease, followed by another increase in intraocular pressure. '353 Patent File History at C0005299-5300, at Niles Decl. Tab 3. The '353 Patent, on the other hand, "provides a decrease which is sustained by periodic administration of prostaglandins." *Id.* C0005300. Plaintiff contends the plain meaning of the claims and Defendants' argument to the PTO supports the conclusion that reduction in intraocular pressure need only be maintained between periodic applications.

Defendants submit that Plaintiff's view that the avoidance of tachyphylaxis and the maintenance of intraocular pressure are distinct goals is incorrect because if tachyphylaxis occurs the drug loses its effectiveness and the reduction of intraocular pressure is lost. Further, they point to three instances in the specification in which the phrase "to maintain reduced intraocular pressure" is defined to include the avoidance of tachyphylaxis. *See* '353 Patent, col. 2, 11-56-58 ("Repeated application, preferably daily, provides long-term reduction of intraocular pressure, without development of tachyphylaxis."); *id.* col. 3, 11.4-10 ("Periodic application of eicosanoids reduces elevated intraocular pressure levels to normal values which continues during the course of treatment without development of tachyphylaxis."); *id.* col. 12, 11.3-6 ("The main focus of this experiment was the demonstration that Pgs can be used to maintain lower intraocular pressure over a prolonged period

of time without the development of tachyphylaxis or tolerance.").

The Court finds the plain meaning of the disputed phrase and the intrinsic evidence support the Defendants' proposed construction. The phrase at issue was the basis for the PTO's eventual issuance of the Patent. Before the PTO approved the patent, Columbia had to insert the following italicized language into the claim: "A method for treating hypertension or glaucoma in a primate subject's eye comprising *periodically* contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure *in the eye without any substantial initial increase in said pressure and to maintain reduced intraocular pressure*." Accordingly, the Court finds that the maintenance of reduced intraocular pressure and the corresponding prevention of tachyphylaxis through period application of prostaglandins is integral to the '353 Patent. Plaintiff's suggestion that the phrase should be interpreted as maintaining lowered intraocular pressure and avoiding tachyphylaxis only between each dosage does not make sense and is not supported by the Patent itself. *See, e.g.*, '353 Patent, col. 2 11.56-58 ("Repeated application, preferably daily, provides long-term reduction of intraocular pressure, without development of tachyphylaxis."). Accordingly, since Defendants' proposed construction of the phrase in claim one is supported by the Patent itself and encompasses the terms' ordinary meaning, the Court adopts Defendants' proposed construction.

Appendix B

C. Co-Inventorship Claim

"Patent issuance creates a presumption that he named inventors are the true and only inventors." *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456 , 1460 (Fed. Cir. 1998) (citing *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997)). A party seeking correction of inventorship "must meet the heavy burden of proving its case by clear and convincing evidence [that] corroborate[s] the alleged joint inventor's conception." *Ely Lilly & Co. v. Aragdigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004) (citing *Ethicon*, 135 F.3d at 1461); *see also Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1318 (Fed. Cir. 2004) (citing *Hess*, 106 F.3d at 979-80). "Reliable evidence of corroboration preferably comes in the form of physical records that were made contemporaneously with the alleged prior invention." *Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed Cir. 2002). Independent circumstantial evidence may also corroborate. *Id.* at 1303. Whether the co-inventor's testimony has been sufficiently corroborated is evaluated under a "rule of reason analysis," which requires a court to consider "all pertinent evidence . . . so that a sound determination of the credibility of the inventor's story may be reached." *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993).

The alleged co-inventor does not have to demonstrate that he made a contribution equal in importance to the contribution made by the listed inventor. *See* 35 U.S.C. § 116 (2000) ("Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount

of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."). Yet, a "person is a joint inventor only if he contributes to the conception of the claimed invention." *Ely Lilly & Co.*, 376 F.3d at 1359 (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998)); *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997) (explaining the claimed joint inventor must make a contribution that is 'not insignificant in quality"); *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994).

"Conception is the touchstone of inventorship, the completion of the mental part of the invention." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994). It is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operate invention, as it is hereafter to be applied in practice." *Hybritech, Inc. v. Monclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (internal citation omitted); *see also Ethicon*, 135 F.3d at 1460 (explaining an idea is sufficiently "definite and permanent" when "only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation"). "One who merely suggests an idea of a result to be accomplished, rather than means of accomplishing it, is not a joint inventor." *Garrett Corp. v. United States*, 422 F.2d 874, 880 (Ct. Cl. 1970); *see also Sewall v. Walters*, 21 F.3d 411, 416-17 (Fed. Cir. 1994); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624 (Fed. Cir. 1985) ("An inventor 'may use the services, ideas and aid of others in the process of perfecting his invention without losing his right to a patent.'") (internal citations omitted). Contribution to an invention in

the form of an explanation of the current "state of the art" does not amount to contribution to conception. *Hess*, 106 F.3d at 981. Similarly, "[o]ne does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention." *Ethicon*, 135 F.3d at 1460; *see also Trovan*, 299 F.3d at 1302; *Fina Oil*, 123 F.3 at 1473.

As will be demonstrated below, a review of the items that Stern argues support his claim for co-inventorship demonstrates a lack of any clear and convincing corroborating evidence that he contributed to the conception of the '353 Patent, i.e., that he made a contribution to the finding that periodic topical applications of prostaglandins would maintain a reduction of intraocular pressure over the course of the drug treatment. *See Linear Tech. Corp.*, 379 F.3d at 1327.

1. *NIH Grant Applications*

To receive federal funding for his research, Dr. Bito submitted proposals to the National Institute of Health ("NIH") in January 1981. Niles Decl. Tab 8. Stern claims the application did not include any reference to any experiments seeking to determine whether prostaglandins could be used to reduce intraocular pressure in primates. Pltf. 56.1 ¶ 54. Stern also claims he completed these experiments during the course of his lab work under Dr. Bito's direction and thereby prompted the ideas that culminated in the '353 Patent.

Appendix B

In fact, the 1981 NIH Application demonstrates that Dr. Bito intended to pursue research on the relationship between prostaglandins and intraocular pressure in primates. *See, e.g.*, 1981 NIH Application, at Niles Decl. Tab 8, C0006706 (indicating rhesus monkeys would be used), C0006742-43 (indicating past findings regarding rhesus monkey eyes' similarities to human eyes and planned future experiments). The Court finds that nothing in the 1981 NIH application supports a finding that Stern contributed to the conception of the invention.

2. *Lab Notebook*

Dr. Bito asked Stern to record his experiments and findings in a grey lab notebook that was to be kept in the lab. Defendants claim the notebook was destroyed when Dr. Bito retired. Stern makes various insinuations that Dr. Bito destroyed the notebook to prevent a co-inventor's status from being revealed. What Stern ignores, however, is that even if his lab notebook did still exist it could not, on its own, corroborate his claim of co-inventorship. *See Hahn v. Wong*, 892 F.2d 1028, 1033 (Fed. Cir. 1989) (explaining alleged co-inventor would need more than lab notebooks to substantiate his claims); *see also* Haile Dep. 162.9-163:7 (Plaintiff's expert explaining she did not know of patent case in which lab notebook on its own supported co-inventorship claim), at Murray Decl.

3. *Rhesus Monkey Paper*

As explained above, Stern wrote a paper summarizing his work in Dr. Bito's lab that qualified him for the McKane Memorial Award and, after undergoing revisions with

Appendix B

Dr. Bito, was eventually published in *Investigative Ophthalmology & Visual Science*. Stern claims that each version of the paper, while similar in substance, is a separate piece of corroborating evidence substantiating his claims for co-inventorship. Stern argues the McKane Award version of the paper was the first document to report on experiments with primates and prostaglandins that indicated prostaglandins may be used to treat glaucoma. Yet in his deposition, Stern stated he did not know who first thought to topically apply prostaglandins to primate eyes to reduce intraocular pressure. *See* Feb. 25, 2002 Stern Dep. 151:17-152:8, at Murray Reply Decl. Ex. C. Additionally, the McKane Award version of the paper cites an earlier article co-authored by Dr. Bito to support the proposition that prostaglandins could be useful in glaucoma treatment. *See* Frederic A. Stern, "Intraocular Pressure Lowering Effect of PGE2 and PGF2cc in the Cat and Rhesus Monkey," Submitted in Consideration for the Edith and Denton McKane Memorial Award, at Niles Decl. Tab 5 C004373 n.11 (citing Camras and Bito owl monkey paper for the proposition that prostaglandins might be useful to treat glaucoma). Plaintiff's own expert also agreed that there is no evidence that Stern was the first to think of topically applying prostaglandins to treat glaucoma. *See* Haile Dep. 171:16-24, at Murray Decl. Stern also believes the fact that he is listed as the first author is significant because in ophthalmology circles it signals who contributed most of the work. Pltf. 56.1 ¶¶ 81-83. Defendants have never disputed that Stern performed the experiments outlined in the rhesus monkey paper. *See, e.g.*, Pltf. 56.1 ¶ 61 (stating that Dr. Bito told the FDA in 1982 that Stern was responsible for the day-to-day studies reflected in the rhesus monkey paper).

Appendix B

Nothing in any version of the rhesus monkey paper demonstrates any contribution by Stern to the conception of the '353 Patent regarding the periodic application of prostaglandins to maintain reduced intraocular pressure. Even if it did, "co-authors may not be presumed to be coinventors merely from the fact of co-authorship." *In re Katz*, 687 F.2d 450, 455 (C.C.P.A. 1982); *see also Coleman v. Dines*, 754 F.2d 353, 360 (Fed. Cir. 1985).

4. *Dr. Bito's Evaluation of and Recommendation on Behalf of Stern*

When Dr. Bito evaluated Stern's work, he stated that Stern did an "excellent job of reviewing literature, [he] wrote the entire first draft of the manuscript, and very significantly contributed to the subsequent revisions and editing . . . [and he] learned [the] kind of thinking that is required for the design of experiments." Niles Decl. Tab 13. In August 1982, Dr. Bito wrote a letter of recommendation to the University of Washington on Stern's behalf stating Stern's work was "an integral part of our studies on the development and use of eicosanoids for the treatment of glaucoma." Niles Decl. Tab 20. While Dr. Bito clearly appreciated the quality of Stern's work, neither of these statements can be read as contemporaneous evidence that Stern conceived the '353 Patent.

5. *Dr. Bito's Consultancy Agreement with Alcon*

In June 1981 Dr. Bito entered into a consultancy agreement with Alcon Laboratories. From this, Stern argues conception of the '353 Patent must have been complete when

he graduated in May 1981 and, therefore, Stern must have contributed to the conception of the invention. The only thing the record actually supports regarding Dr. Bito's consultancy agreement with Alcon is that the company engaged Dr. Bito because he was published in the areas of inflammation and glaucoma. *See* Dep. of Dr. Louis DeSantis, Alcon Vice President Product Support, 33:3-19, at Niles Decl. Tab 63. Contrary to Stern's suggestions, the record does not support the finding that Dr. Bito was eager to market his findings and rushed into an agreement with Alcon to do so. *Id.* 33:16-19 (Dr. DeSantis stating there was no specific aspect of glaucoma research that Alcon was interested in hearing about from Dr. Bito).

6. *Dr. Bito's Receipt of Proctor Award*

Dr. Bito received the Proctor Award in 2000, which is apparently the equivalent of the Nobel Prize in ophthalmology, for his work in glaucoma research. Stern finds three things in Dr. Bito's acceptance paper noteworthy. First, Dr. Bito noted that the 1978 owl monkey data was disappointing. Second, Dr. Bito did not mention the Stern and Bito rhesus monkey paper. And third, Dr. Bito acknowledged that medical students contributed to "concepts" resulting in the development of the glaucoma treatment Xalatan. Pltf. 56.1 ¶¶ 70-74. This paper does not provide corroborating evidence that Stern contributed to the conception of the '353 Patent. It simply demonstrates that owl monkeys were not the right model for Dr. Bito's prostaglandin research and that medical students performed experiments under Dr. Bito's direction.

Appendix B

D. State Law Claims

In his state law fraud claim, Stern contends that Defendants intentionally concealed the Patent application from him, knowing he was an omitted co-inventor. Complaint ¶¶ 41-46. In his breach of fiduciary duty claim, Stern claims that Bito, as his advisor and purported co-inventor, owed him a duty of listing him as a co-inventor. *Id.* ¶¶ 36-40. Finally, Stern claims the Defendants were unjustly enriched by receiving royalties from the Patent, in which Stern should have been included as a co-inventor. *Id.* Each of these claims requires a finding that Stern is in fact an omitted co-inventor. Since Stern cannot survive summary judgment on his claim for co-inventorship, his state law claims for fraudulent concealment, breach of fiduciary duty, unjust enrichment also fail.

III. Conclusion

For the reasons explained above, Defendants' motion for summary judgment is granted in its entirety. The Clerk of Court is asked to close the case.

So Ordered: New York, New York
February 17, 2005

s/ Richard Conway Casey
Richard Conway Casey, U.S.D.J.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR PANEL REHEARING AND PETITION FOR REHEARING EN BANC DATED MARCH 9, 2006

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1291

FREDRIC A. STERN,

Plaintiff-Appellant,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK and LASZLO Z. BITO,

Defendants-Appellees.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Appellees, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

Appendix C

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on March 16, 2006.

FOR THE COURT,

/s/
Jan Horbaly Clerk

Dated: March 9, 2006